

REMARKS

Claims 1-61 are pending. Claims 1-28 and 53-58 were not elected and are canceled without prejudice. Claims 17-25 were previously canceled without prejudice.

Claims 29-39, 41, 42, 44-52, and 59-61 are rejected. Claims 40 and 43 are objected to. Claims 35 and 44 are amended; the amendments are fully supported in the application as filed and introduce no new matter. New claims 62 and 63 are claims 40 and 43, respectively, rewritten as independent claims

Applicant thanks the Examiner for the January 9, 2007 personal interview with Applicants' undersigned representative. As required, Applicants state that the substance of the interview was the pending claims and how Applicant's claimed method distinguishes over Chen.

CLAIM OBJECTIONS

Claim 44 is objected to as depending from a canceled claim. Applicant has corrected claim 44 as requested, overcoming this objection.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 29-39, 41, 45-52, and 59-61 are rejected under 35 U.S.C. §102(b) as anticipated by Chen. Applicant respectfully disagrees and submits with this Amendment a Declaration under §1.132 that includes data supporting Applicant's position.

Each of Applicant's claims 29-39, 41, and 45-52 recite methods for isolating "purified RNA". Applicant has specifically defined "purified RNA": it is RNA that is substantially undegraded and free of DNA contamination when assayed by reverse transcriptase polymerase chain reaction (RT-PCR) (p. 7, lines 10-12).

Chen's method does not isolate "purified RNA", and thus does not anticipate Applicant's claims. Chen "provides a total RNA extraction reagent and manufacturing method that can shorten the time, simplify manufacturing, and improve effectiveness of extracting total RNA (including rRNA, tRNA, and mRNA), as well as an RNA extraction method with simpler operation and quicker results" (Examiner's translation p. 5 bottom to p. 6 top). Chen's method shortens and simplifies the method of RNA isolation; it does not isolate purified RNA as Applicant has defined it. DNA-free RNA cannot be isolated using Chen's method; it is adequate for RNA analysis using the Northern blotting technique, but not the more sensitive technique of reverse transcription-PCR (RT-PCR), which requires higher purity RNA.

Applicant's Declaration provides analysis with supporting data demonstrating how and why Chen's method does not isolate purified RNA.

Because Chen does not disclose a method for isolating purified RNA, which Applicant has defined as RNA that is substantially undegraded and free of DNA contamination when assayed by RT-PCR, Chen does not anticipate Applicant's method of claims 29-39, 41, 45-52, and 59-61.

Further with respect to claims 59-61, the claimed method requires treating the sample with a composition containing "...at least one water-soluble organic solvent at a concentration from about 10% w/w to about 40% w/w to selectively precipitate higher molecular weight RNA from the sample".

Chen's method does not use a reagent containing a water-soluble organic solvent, nor does it selectively precipitate higher molecular weight RNA.

Chen's reagent contains phenol, buffer, and a chaotrope. Chloroform is then added to the reagent and phase separation is performed. RNA is sequestered into the aqueous phase and separated from DNA and proteins. This RNA is precipitated from the aqueous phase with alcohol, but this is not selective precipitation, as claim 59 recites, because DNA and proteins are already removed from the aqueous phase during phase separation. Thus, any DNA or proteins contaminating the aqueous phase are precipitated together with the RNA.

In contrast, claim 59 recites an organic solvent to selectively precipitate RNA from the solution containing other molecules. This occurs without adding chloroform and without phase separation.

For at least these reasons, Applicant respectfully asserts that the rejections under 35 U.S.C. §102 are completely overcome, and respectfully requests that the rejection be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

Claim 42 is rejected under 35 U.S.C. §103(a) as obvious over Chen in view of Chomczynski '994. Claim 44 is rejected under 35 U.S.C. §103(a) as obvious over Chen in view of Puissant. Applicant respectfully disagrees with both rejections.

There is no teaching, suggestion, or motivation in Chen that it results in purified RNA, as Applicant has defined it and for the reasons analyzed above. Thus, the primary reference fails so that the secondary references are not supported.

The addition of Chomczynski '994 is a specific teaching away from a method resulting in purified RNA:

The reagents and methods described in the '155 and '994 patents provide substantially pure, undegraded RNA. However, RNA isolated according to the '155 and '994 patents contains a residual amount of genomic DNA, which can be detected by reverse transcription-polymerase chain reaction assay (RT-PCR). Thus, RNA isolated in accord with the '155 and '994 patents must be further purified to render it DNA-free (p. 2, lines 16-21) (citations omitted).

Applicant's data in the attached Declaration demonstrate that Applicant's method results in purified RNA.

For at least these reasons, Applicant believes he has overcome the rejection and respectfully requests its withdrawal.

CONCLUSION

Applicant believes the application is in complete condition for allowance, and does not believe there is any fee due with this submission. However, if any fees are required, the Examiner is authorized to charge the fees to Deposit Account No. 23-3000.

The Examiner is invited to telephone Applicant's undersigned representative with questions.

Respectfully submitted,

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